

Round Table 8: Diagnostics Market Intelligence in Africa

“HIV Market Intelligence”

ASLM2014

December 2, 2014

Cape Town, South Africa



Testing Forecasts

Market Segmentation

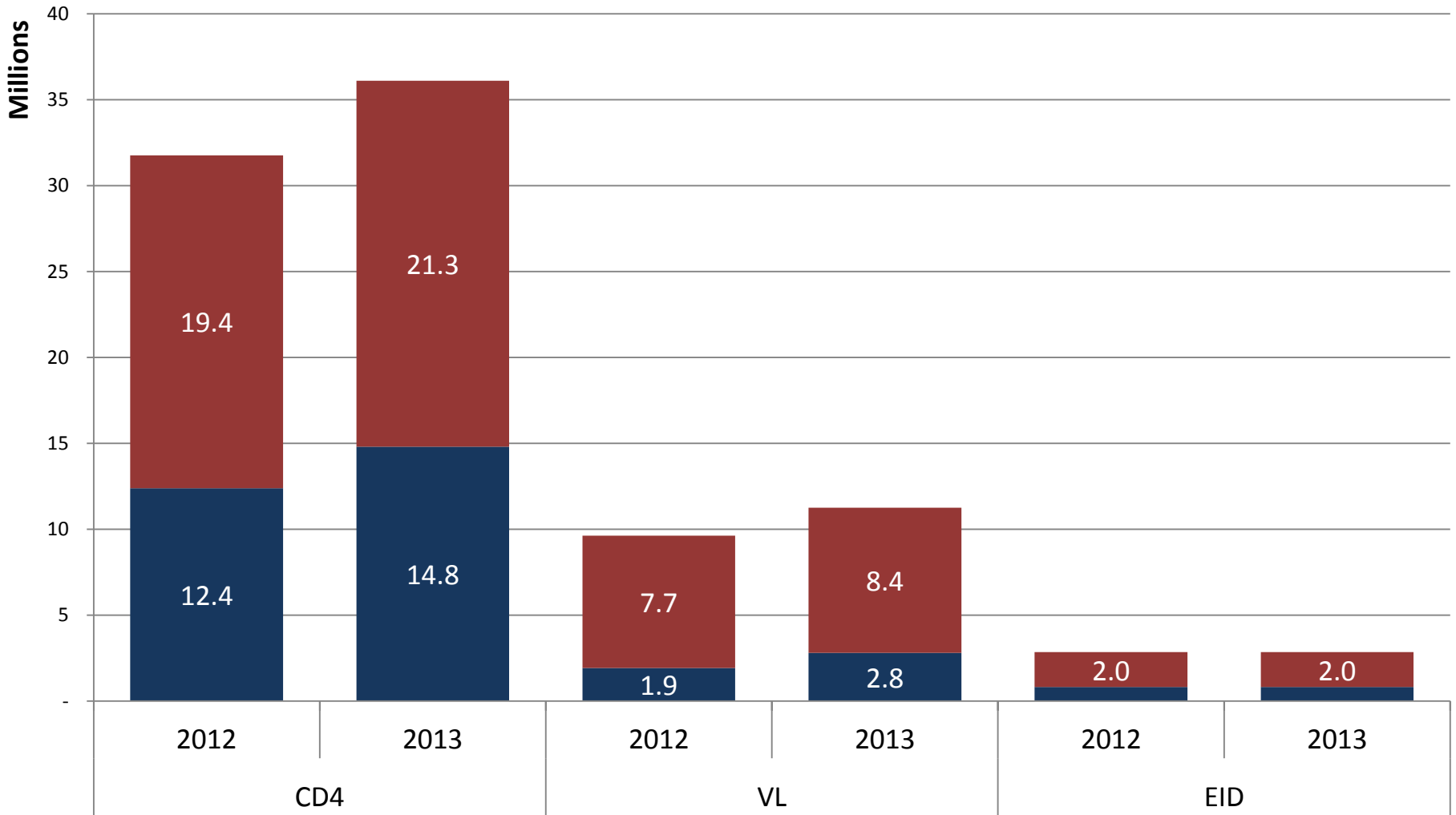
Pricing Analysis

Improving Service Delivery Through Market Intelligence

While HIV diagnostic testing volumes are growing, they still lag far behind full patient need

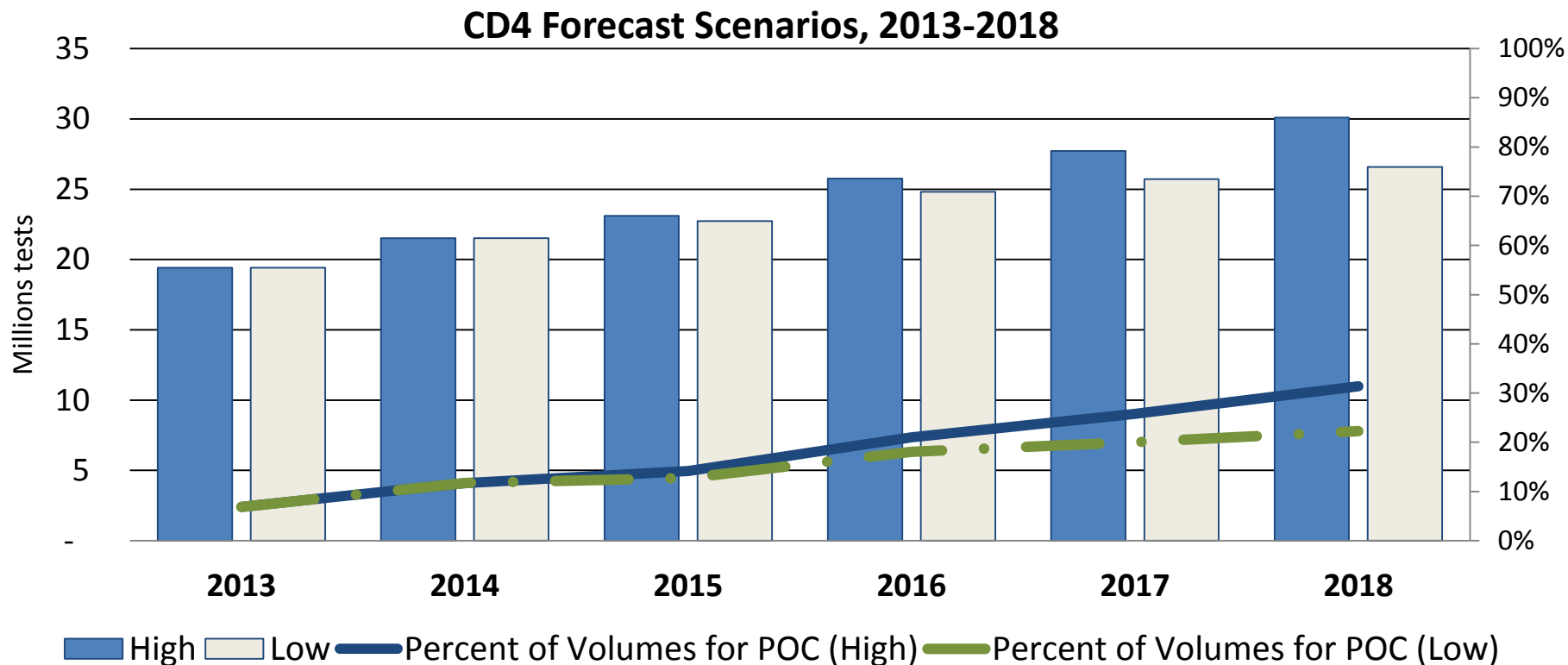
Unmet Need for HIV Diagnostics

■ Number of Tests performed ■ Additional Tests required



¹Need defined as tests required for all patients already enrolled in HIV care for CD4 and Viral Load, and tests required for all HIV-exposed infants for EID

The CD4 market can be forecasted using high- and low-growth scenarios driven by the pace of POC adoption, funding availability, and transition to VL

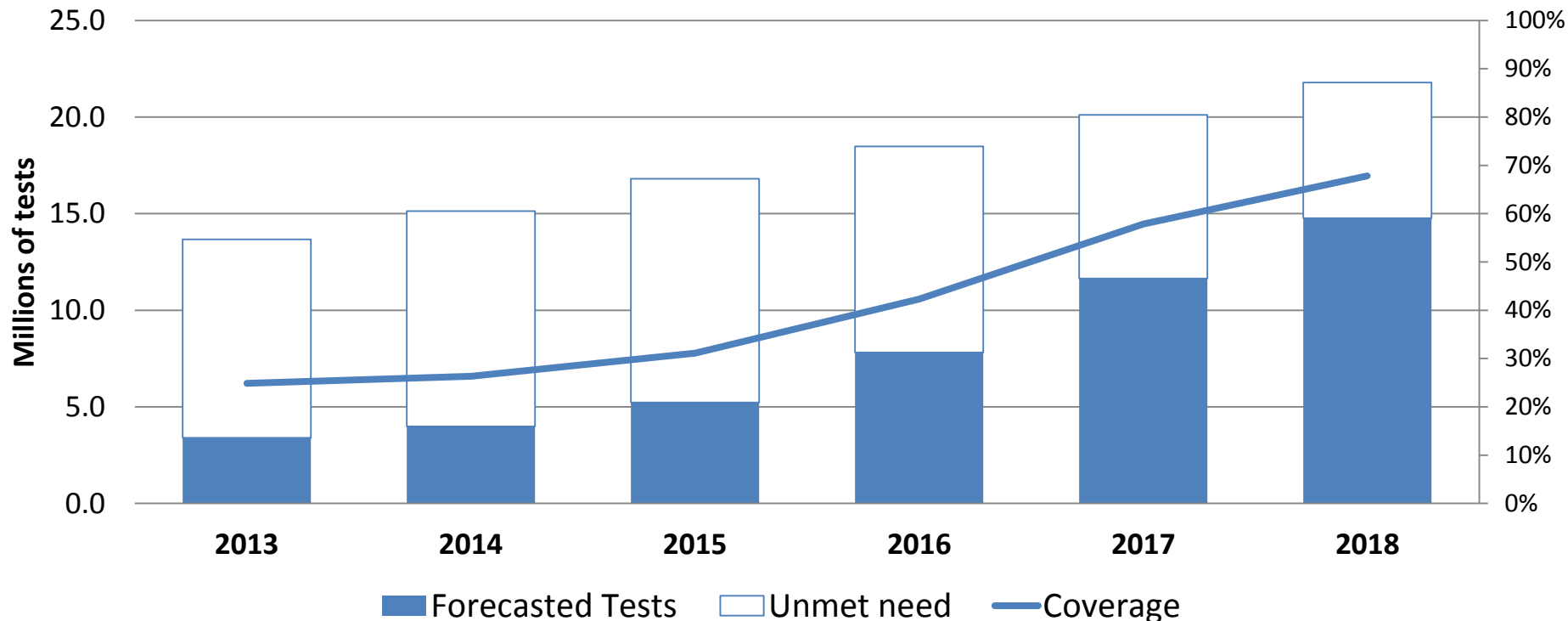


The largest increase in CD4 test volumes will be driven by the adoption of POC devices and device-free technologies in either scenario.

Source: CHAI CD4 forecast, with Laboratory based testing volumes based on CD4 testing coverage data from 21 high HIV-burden countries
Excludes money spent to expand install base of instruments

Although VL coverage remains low, countries are adopting 2013 WHO guidelines and investing in scale-up

Projected Viral Load Tests, 2013-2018



The forecasted testing gap is a factor of funding, country support for widespread scale-up, challenges in extending access beyond existing sample transportation systems, and the speed of clinical uptake.

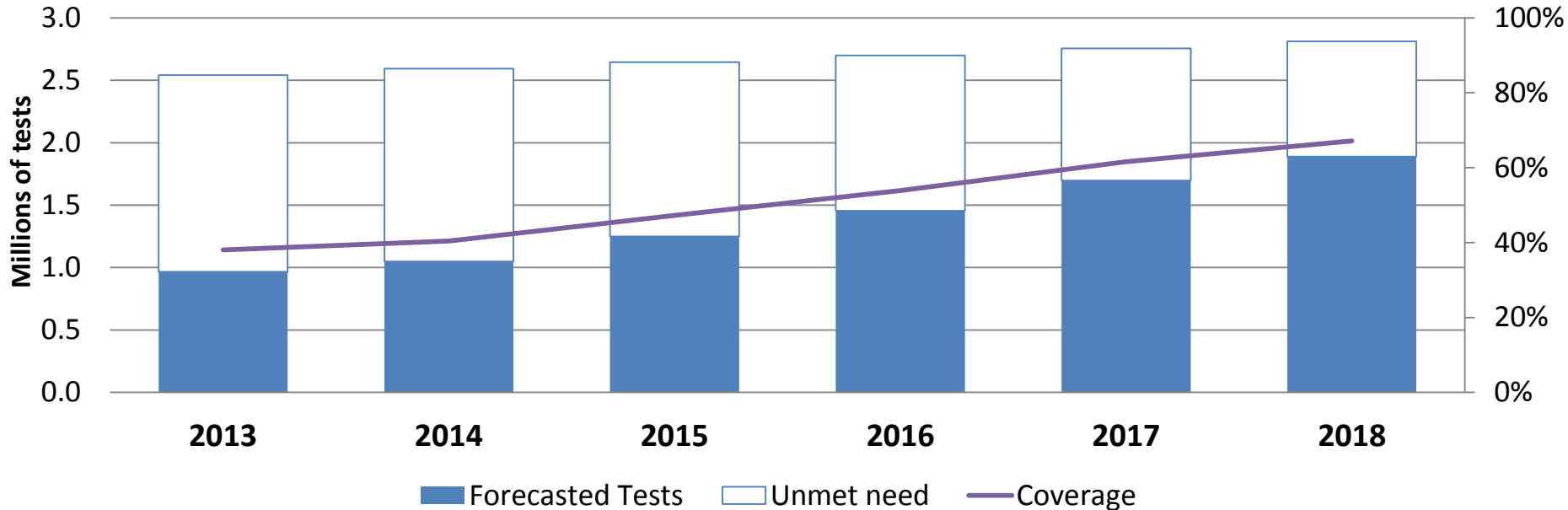
Many countries have a large installed base of PCR equipment, and have established aggressive VL scale-up plans

Country	# PCR Instruments	Tests in 2013	Scale-Up Plans		
			2014	2015	2016
Country 1	13	5,500	71,132	174,426	227,725
Country 2	12	70,000	100,000	150,000	200,000
Country 3	12	34,667	87,000	123,000	170,000
Country 4	27	71,500	100,000	125,000	150,000
Country 5	6	9,918	12,534	14,121	32,823
Country 6	6	31,829	100,000	200,000	400,000
Country 7	3	11,000	11,000	119,976	230,755
Country 8	7	7,000	50,000	TBD	TBD
TOTAL	86	241,416	531,666	906,523	1,411,303

NOTE: # PCR instruments only includes those placed in public sector labs; many countries plan to add additional instruments in the coming year.

EID coverage is projected to fall far short of the total need for testing based on current funding, country plans, and market conditions

Forecasted EID Tests, 2013-2018



Market Trends

- Coverage of EID remains low in most countries due to poor patient retention, weak sample transport systems
- Many infants are not captured by existing PMTCT systems, so additional entry points are needed to improve case-finding
- Viral load uptake will continue to drive investment in strengthening sample transportation networks, which may also lead to gains in EID volumes

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CD4 Market Segmentation: Pre-ART patient population from 7 high burden countries has been segmented over two dimensions

Poor on-site CD4 coverage
 Medium on-site CD4 coverage
 Good on-site CD4 coverage

Market Segmentation by facility level and pre-ART patient population

Criteria	Provincial Hospitals	District Hospitals	Health Centers	TOTAL
>20 Patients per Day				
10-20 Patients per Day				
5-10 Patients per Day				
0-5 Patients per Day				
TOTAL				

Segmentation by level of health facility

CD4 Market Segmentation: Pre-ART patient population from 7 high burden countries has been segmented over two dimensions

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Market Segmentation by facility level and pre-ART patient population

Criteria	Provincial Hospitals	District Hospitals	Health Centers	TOTAL
>20 Patients per Day				
10-20 Patients per Day				
5-10 Patients per Day				
0-5 Patients per Day				
TOTAL				

Segmentation by number of patients visiting the clinic per day on average

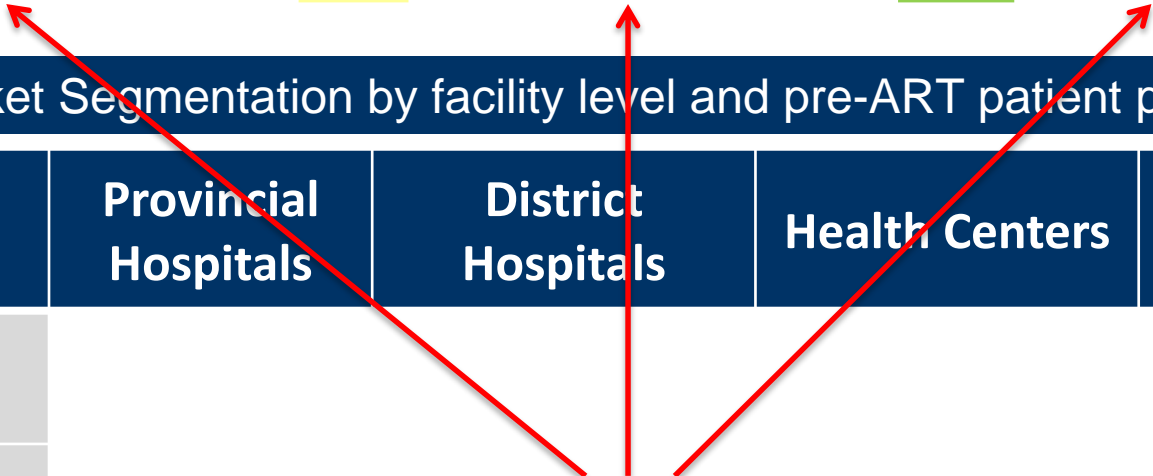
CD4 Market Segmentation: Pre-ART patient population from 7 high burden countries has been segmented over two dimensions

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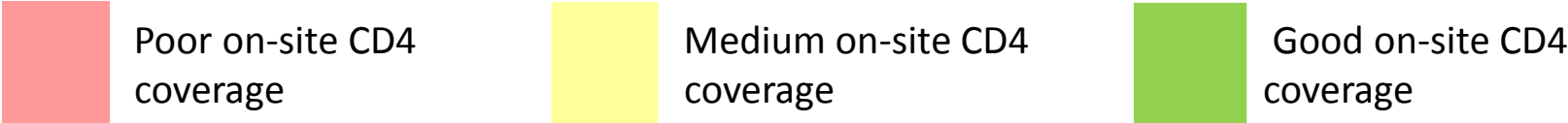
Market Segmentation by facility level and pre-ART patient population

Criteria	Provincial Hospitals	District Hospitals	Health Centers	TOTAL
>20 Patients per Day				
10-20 Patients per Day				
5-10 Patients per Day				
0-5 Patients per Day				
TOTAL				

Colors show the access to on-site CD4 coverage



Onsite CD4 coverage is poor across a range of facility types and sizes; improvements in both high and low-throughput settings are needed



Market Segmentation by facility level and pre-ART patient population for 7 CHAI UNITAID Countries

Criteria	Provincial Hospitals	District Hospitals	Health Centers	TOTAL
>20 Patients per Day	10%	9%	13%	32%
10-20 Patients per Day	2%	10%	11%	23%
5-10 Patients per Day	<1%	6%	10%	16%
0-5 Patients per Day	<1%	6%	23%	29%
TOTAL	12%	31%	57%	100%

EXAMPLE COUNTRY A – LOW DECENTRALIZATION:

Most patients seek care at District Hospitals



Poor on-site CD4 coverage



Medium on-site CD4 coverage



Good on-site CD4 coverage

Market Segmentation by facility level and pre-ART patient population

Criteria	Provincial Hospitals	District Hospitals	Health Centers	TOTAL
>20 Patients per Day	17%	13%	4%	34%
10-20 Patients per Day	<1%	17%	8%	26%
5-10 Patients per Day	<1%	11%	5%	16%
0-5 Patients per Day	0%	8%	16%	24%
TOTAL	18%	49%	33%	100%

EXAMPLE COUNTRY B – HIGH DECENTRALIZATION:

Most patients seek care at Health Centers



Poor on-site CD4 coverage



Medium on-site CD4 coverage



Good on-site CD4 coverage

Market Segmentation by facility level and pre-ART patient population

Criteria	Provincial Hospitals	District Hospitals	Health Centers	TOTAL
>20 Patients per Day	9%	3%	25%	37%
10-20 Patients per Day	3%	9%	11%	23%
5-10 Patients per Day	0%	6%	8%	14%
0-5 Patients per Day	0%	4%	22%	26%
TOTAL	12%	22%	66%	100%

VL Market Segmentation: Based on ART patient population in 7 high burden countries

Market Segmentation by facility level and **ART patient population**

Criteria	Provincial Hospitals	District Hospitals	Health Centers	TOTAL
>20 Patients per Day	8%	7%	15%	30%
10-20 Patients per Day	2%	9%	14%	24%
5-10 Patients per Day	<1%	6%	10%	17%
0-5 Patients per Day	<1%	5%	24%	29%
TOTAL	10%	27%	63%	100%

EID Market Segmentation: Based on number of HIV-exposed infants in PMTCT settings in 3 high burden countries

Market Segmentation by facility level and **PMTCT patient population**

Criteria	Provincial Hospitals	District Hospitals	Health Centers	TOTAL
>10 Patients per Day	<1%	8%	2%	10%
5-10 Patients per Day	2%	6%	3%	10%
1-5 Patients per Day	2%	11%	19%	31%
0.2-1 Patients per Day	<1%	6%	30%	36%
0-0.2 Patients per Day	0%	1%	11%	12%
TOTAL	4%	31%	65%	100%

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Viral Load Access Pricing



\$9.40
reagents + consumables



Media Release

Basel, 26 September 2014

Roche launches Global Access Program for HIV viral load testing

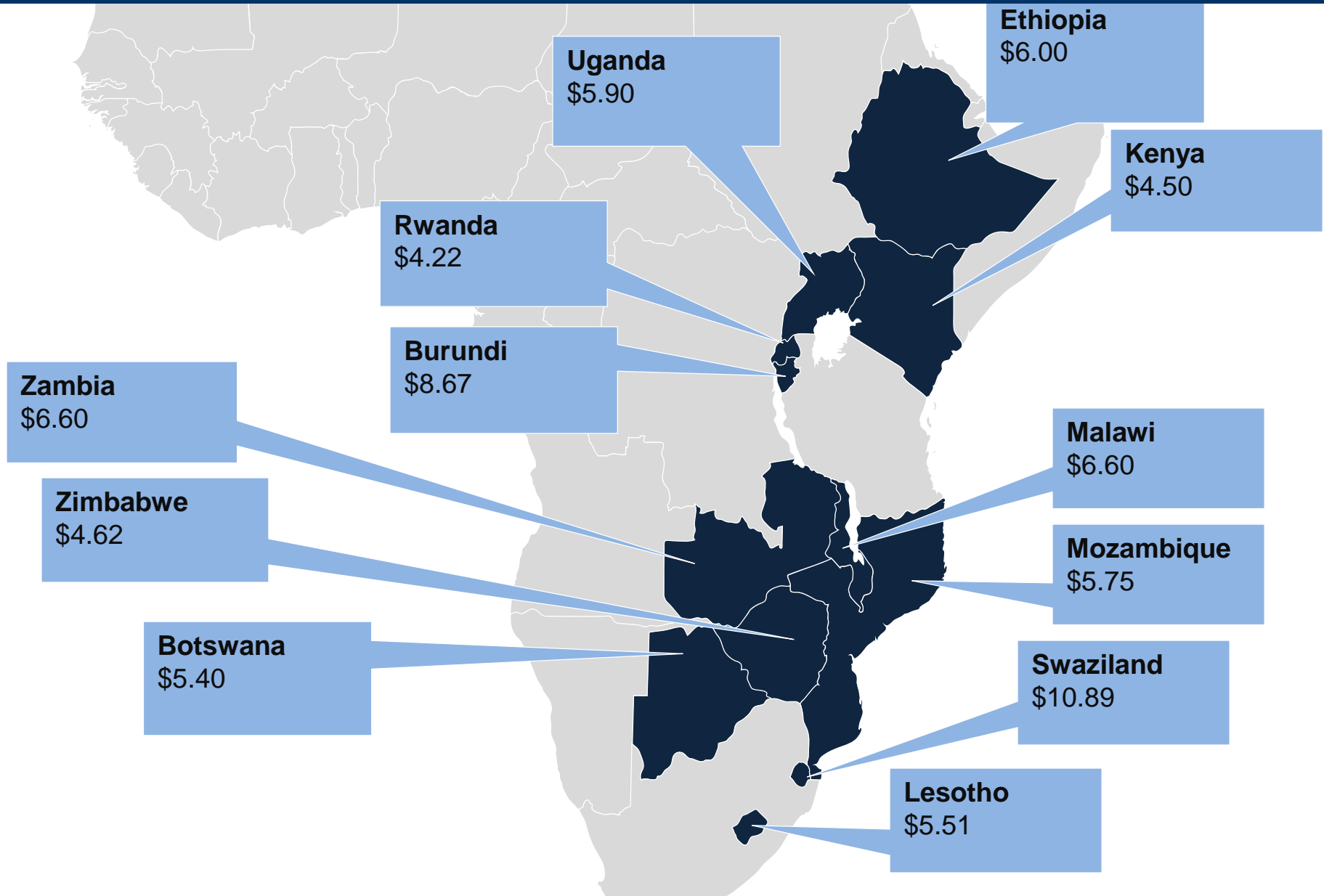
Program expands access to care supporting the Diagnostics Access Initiative

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today the launch of a new Global Access Program for HIV viral load testing, created in partnership with UNAIDS, the joint United Nations Programme on HIV/AIDS, the Clinton Health Access Initiative (CHAI), the President's Emergency Plan For AIDS Relief (PEPFAR) and the Global Fund to fight AIDS, TB & Malaria, at a high-level side event held during the 69th session of the United Nations General Assembly in New York, USA.

- **40% reduction in price**
- **\$150 million in costs savings over 5 years**
- **Dramatic improvement to the quality of care for over 31 million people living with HIV in LMICs**



Lab-based CD4 prices vary significantly by country, with large countries often enjoying considerable discounts



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CHAI gathers market intelligence to facilitate information sharing between suppliers, MOHs, and other stakeholders to improve service delivery

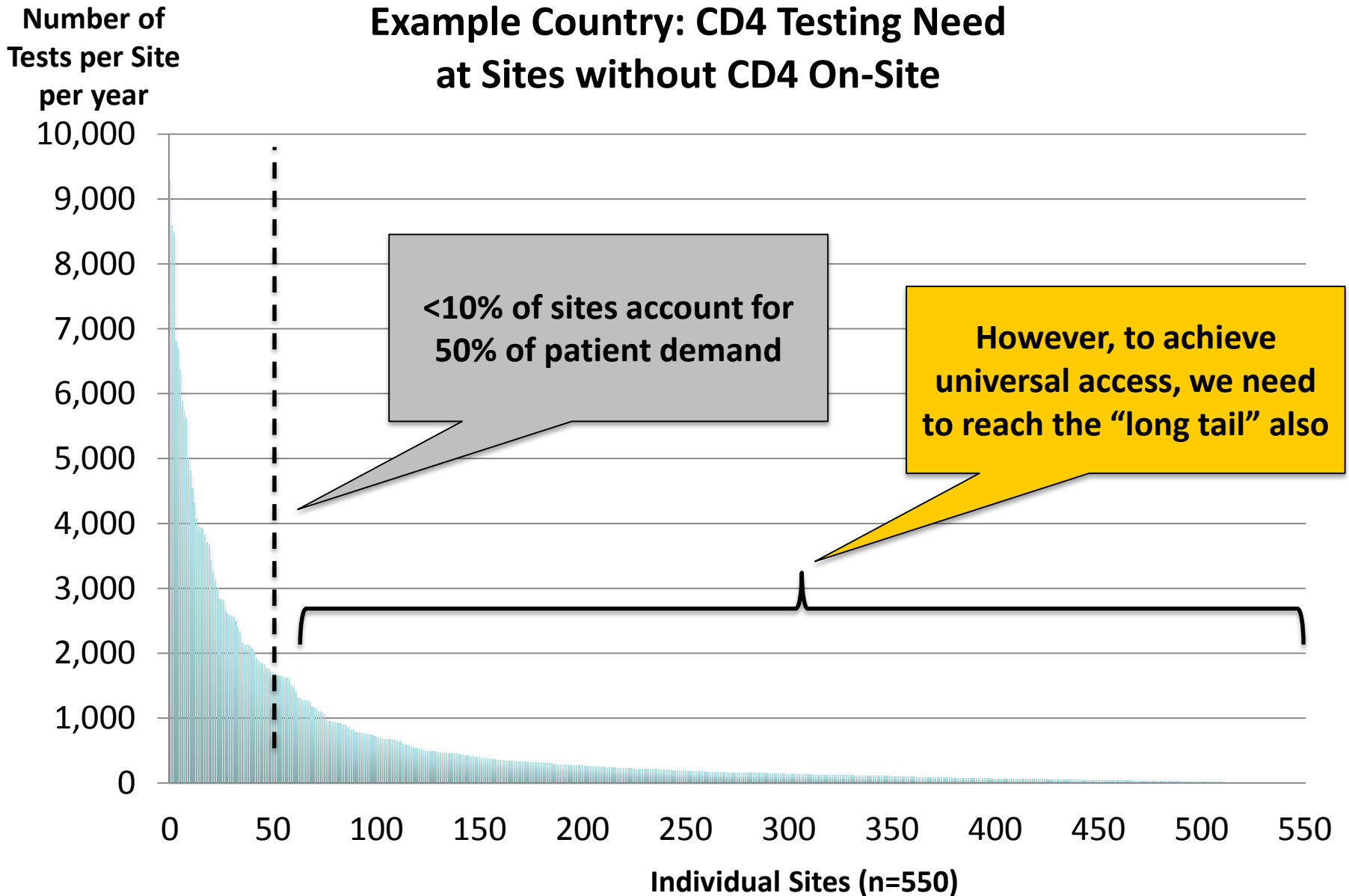
Market Intelligence Data
• Regulatory landscape
• Product evaluation results
• Customer product selection criteria
• Product post-market surveillance
• Testing volumes and forecasts
• Market segmentation
• Market share
• Funding landscape
• Pricing



Key Benefits
• Accelerates market entry
• Accelerates regulatory approval
• Informs design inputs for new products
• Improves after-sale support and new product development
• Drives economies of scale in manufacturing, and lowers prices
• Informs product design (e.g. throughput, infrastructure, etc.)
• Informs product and site selection
• Ensures competitive balance
• Ensures sustainable financing and prompt payment to suppliers
• Ensures transparency and fairness across countries

Example: Market segmentation benefits MOHs by informing optimal deployment of new and existing products...

Example Country: CD4 Testing Need at Sites without CD4 On-Site



...And benefits suppliers by providing insight into customers' needs to inform product design and after-sale support

CD4 Testing Need	Country A	Country B	Country C	Country D	Country E	Country F	TOTAL
Distribution of Patients							
>20 Tests per Day	30%	54%	0%	73%	53%	11%	50%
10-20 Tests per Day	30%	20%	8%	17%	20%	26%	21%
5-10 Tests per Day	21%	13%	15%	7%	15%	20%	14%
1-5 Tests per Day	17%	12%	54%	3%	12%	36%	14%
<1 Test per Day	1%	1%	24%	0%	1%	7%	2%
Distribution of Sites							
>20 Tests per Day	7%	9%	0%	35%	9%	1%	8%
10-20 Tests per Day	13%	11%	2%	24%	12%	5%	10%
5-10 Tests per Day	19%	14%	4%	21%	18%	7%	13%
1-5 Tests per Day	44%	36%	32%	18%	39%	37%	35%
<1 Test per Day	16%	30%	62%	2%	22%	50%	34%

Both high- and low-throughput CD4 products are needed

Thank You

- MOHs – Ethiopia, Kenya, Malawi, Mozambique, Tanzania, Uganda, Zimbabwe
- Zach Katz, Charles Kasipo, Paolo Maggiore, Meghan Wareham

